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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,745	12/21/2001	Keiichi Kawai	Q67507	2602

7590 02/24/2004

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EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,745	KAWAI ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 11/24/03 wherein claims 17, 19, 22, and 27 were amended.

Note: Claims 14-29 are pending.

RESPONSE TO APPLICANT'S COMMENTS ABOUT THE RESTRICTION

2. Applicant's acknowledgment of the Examiner's request to amend the claims such that verapamil is the second drug as set forth in the elected invention for prosecution is noted. However, Applicant has deferred from making the amendment to the claims in the hopes that the search will be extended to cover non-elected subject matter. As previously stated, the rejection has been made final and only the elected invention will be searched. Thus, Applicant is once again respectfully requested to cancel the non-elected subject matter.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

3. The Applicant's arguments filed 11/24/03 to the rejection of claims 14-29 made by the Examiner under 35 USC 102, 103, and/or 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 Rejections

The 112, first and second, paragraph rejections are WITHDRAWN for reasons of record in Applicant's response.

102 Rejections

Note: The 102 rejection over Pritchard et al is MAINTAINED-IN-PART for the reasons of record in the office action mailed 6/23/03 and those set forth below.

I. The rejection of claims 14, 15, and 20 under 35 USC 102(b) as being anticipated by Pritchard et al (J. Clin. Pharmacol., 1985, Vol. 25, pages 347-353) is MAINTAINED.

Applicant asserts that Pritchard et al does not teach the instant invention because the amount of verapamil necessary to affect the binding is greater than amounts that are clinically employed.

Applicant's independent claim 14 reads on in vivo and in vitro methods (note that claims 16-19 and 21-29 are directed to in vivo method or compositions). However, claims 14, 15, and 20 are not limited to in vivo administration; thus, there are no requirements that the amounts administered be pharmaceutically acceptable or an effective amount. The method simply requires the administration of a first drug and a single/plural second drug wherein both drugs have binding affinity for the same plasma protein. Hence, Applicant's argument regarding the amount of verapamil administered is not persuasive.

II. The rejection of claims 14-17, 20, 21, 23, 25, 28, and 29 under 35 USC 102(b) as being anticipated by Somogyi et al (Br. J. Clin. Pharmac., 1981, Vol. 12, pages 51-60) is MAINTAINED for reasons of record in the office action mailed 6/23/03 and those set forth below.

Applicant stated that the Examine is of the opinion that both the intravenous dose and oral dose of verapamil are administered simultaneously in Somogyi et al.

On page 52, columns 1-2, bridging paragraph, it is disclosed that verapamil was administered both by intravenous and oral route simultaneously using stable labeled techniques. The intravenous (unlabeled) dose was given at a constant infusion of 10 mg verapamil dissolved in 10 ml of physiological saline over five minut3es and the oral dose of 40 mg HCl consisted of d3-verapamil given in solution form 30 minutes after the end of the intravenous infusion. Furthermore, Somogyi et al disclose that the control subjects received the same intravenous doses, but 80 mg d3-verapamil orally.

Applicant asserts that Somogyi et al do not discuss binding to plasma protein, but only mentions the binding to plasma protein in item 4 of the abstract and the discussion on page 55.

Applicant's attention is directed to page 52, the section titled "Plasma protein binding and erythrocyte distribution".

103 Rejections

I. The 103 rejection over Pritchard et al is WITHDRAWN for reasons of record in Applicant's response.

II. The rejection of claims 14 and 16-29 under 35 USC 103(a) as being unpatentable over Somogyi et al (Br. J. Clin. Pharmacol., 1981, Vol. 12, pages 51-60) in view of Li et al (US Patent No. 5,977,163) is MAINTAINED for reasons of record in the office action mailed 6/23/03 and those set forth below.

Applicant's assertions regarding the 103(a) rejection over Somogyi et al are set forth and addressed above in the 102(b) rejection section.

SPECIFICATION

4. Applicant is correct that the application was not filed under 37 CFR 1.60. However, Applicant is respectfully requested to insert the continuing data in the first line of the specification. Specifically, Applicant is requested to insert the phrase 'This application is a 371 of PCT/JP00/04039 filed 6/21/00.'.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1616

February 20, 2004